

EXHIBIT A

08:54:02

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

NYCOMED GMBH, et al.

Case No. 1:09-cv-04999

Plaintiffs

Chicago, Illinois

November 23, 2009

v.

Initial Status Conference

APOTEX INC., et al.,

Defendants.

TRANSCRIPT OF INITIAL STATUS CONFERENCE
BEFORE THE HONORABLE VIRGINIA M. KENDALL
UNITED STATES DISTRICT JUDGE

APPEARANCES:

For the Plaintiff:

Paul Hastings Janofsky & Walker LLP

By: Joseph M. O'Malley, and

Isaac S. Ashkenazi

75 E. 55th Street

New York, NY 10022

(212) 318-6000

- and -

Paul Hastings Janofsky & Walker LLP

By: Ericka K. Foster

191 N. Wacker Drive

Chicago, IL 60606

(312) 499-6018

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2

3 APPEARANCES (Cont'd):

4

For the Plaintiff (Cont'd):

5

- and -

6

Wilmer Cutler Pickering Hale and Dorr
By: William G. McElwain
1875 Pennsylvania Ave. NW
Washington, DC 20006
(202) 663-6000

9

10

11 For the Defendants:

Husch Blackwell Sanders Welsh & Katz
By: Steven E. Feldman, and
Sherry L. Rollo, and
James P. White
120 S. Riverside Plaza
Chicago, IL 60606
(312) 655-1500

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16

COURT REPORTER:

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FEDERAL OFFICIAL COURT REPORTER
April M. Metzler, RPR, CRR
219 South Dearborn St., Rm. 2318-A
Chicago, IL 60604
(312) 408-5154
April_Metzler@ilnd.uscourts.gov

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09:01:24 1 (Commenced at 9:01 a.m.)

09:01:24 2 THE CLERK: 09C4999, Nycomed GmbH, et al. versus

09:01:30 3 Apotex Inc., et al.

09:01:39 4 MR. FELDMAN: Good morning, your Honor. Steve

09:01:40 5 Feldman and Sherrie Rollo and Jim White on behalf of Apotex.

09:01:44 6 THE COURT: Good morning.

09:01:44 7 MR. WHITE: Good morning, your Honor.

09:01:45 8 THE COURT: Good morning.

09:01:46 9 MR. O'MALLEY: Good morning. Joe O'Malley, Paul

09:01:48 10 Hastings, on behalf of the plaintiffs, Nycomed and Wyeth.

09:01:52 11 THE COURT: Good morning.

09:01:52 12 MR. O'MALLEY: With me is ...

09:01:53 13 MR. McELWAIN: Bill McElwain from Wilmer Hale also

09:01:56 14 for the plaintiff.

09:01:56 15 MS. FOSTER: Erica Foster.

09:01:58 16 THE COURT: Good morning.

09:01:58 17 MR. ASHKENAZI: Isaac Ashkenazi.

09:02:00 18 THE COURT: Good morning. Must be a patent case,

09:02:02 19 right?

09:02:02 20 (Laughter.)

09:02:03 21 THE COURT: Only my 21st, I think, for the docket.

09:02:07 22 Okay, folks. Tell me a bit about your case.

09:02:10 23 Plaintiffs first.

09:02:11 24 MR. O'MALLEY: Your Honor, this is a so-called

09:02:15 25 Hatch-Waxman Act patent case, and we're aware that you've had

09:02:19 1 them before.

09:02:19 2 This case involves our client's drug product
09:02:23 3 PROTONIX. It's a proton pump inhibitor. Treats acid reflux.
09:02:28 4 It's in the same class of drugs as Prilosec. You might have
09:02:30 5 seen the ads for Prilosec.

09:02:31 6 THE COURT: Right.

09:02:32 7 MR. O'MALLEY: Prior to the generic launch, this was
09:02:34 8 a \$2 billion a year drug product. As you're familiar with the
09:02:39 9 procedure in these ANDA cases, a generic who wants to copy the
09:02:43 10 drug files a so-called Abbreviated New Drug Application.

09:02:47 11 When they do that, they have to make a certification
09:02:52 12 with respect to each of the patents that the branded company
09:02:54 13 listed in the so-called Orange Book [sic].

09:02:56 14 With respect to this case, the patent at issue is the
09:03:01 15 so-called '579 patent, that is an active ingredient patent.
09:03:06 16 The active ingredient patent is always the crown jewel in the
09:03:10 17 patent portfolio of the branded company.

09:03:12 18 With respect to this '579 patent, about seven or
09:03:17 19 eight generics originally decided to respect the patent. They
09:03:21 20 filed a so-called paragraph 3 certification.

09:03:23 21 THE COURT: Right.

09:03:23 22 MR. O'MALLEY: Originally, defendant Apotex, decided
09:03:27 23 to respect the patent. They filed their ANDA, their
09:03:33 24 Abbreviated New Drug Application, in 2008, and at that time
09:03:35 25 they filed a paragraph 3 certification. Only a year later and

09:03:40 1 recently in July they changed that paragraph 3 to a paragraph
09:03:45 2 4 certification.

09:03:47 3 Now, as you may be aware from the materials that the
09:03:50 4 parties submitted, this patent has been litigated on behalf of
09:03:56 5 the plaintiffs and three generics who challenged it in the
09:04:00 6 District of New Jersey now for five years. Originally the
09:04:02 7 case started in 2004. It's now three consolidated cases
09:04:07 8 against three generics.

09:04:09 9 That case is going to go trial sometime in the first
09:04:14 10 quarter of 2010. We don't have a trial date. The parties
09:04:18 11 have a deadline to submit dates that they're available in the
09:04:21 12 first quarter. We've done that. We've recommended a date in
09:04:26 13 January with a backup date sometime in early March or the end
09:04:29 14 of February. The other parties have not yet submitted their
09:04:33 15 letters with trial dates.

09:04:36 16 It's our belief, your Honor, that that litigation
09:04:40 17 will control the fates of all the generics who have filed
09:04:44 18 ANDA. And the way that works, your Honor, if you're not
09:04:48 19 familiar with it, is let's assume that in that Jersey action,
09:04:53 20 the '579 patent is invalidated in a way that collaterally
09:04:57 21 estops us.

09:04:59 22 If that happens, all the generics who did not
09:05:02 23 challenge it will then convert their so-called paragraph 3 to
09:05:05 24 a paragraph 4, and then shortly thereafter the FDA will
09:05:11 25 approve those generics and they could go on the market.

09:05:15 1 We, plaintiffs, are not really sure why Apotex, one,
09:05:20 2 waited after filing their ANDA, but then more fundamentally,
09:05:25 3 why have they challenged it now? Because it's very hard to
09:05:29 4 see any scenario by which you can grant them any meaningful
09:05:35 5 relief.

09:05:36 6 And what I mean by that, your Honor, is if you do not
09:05:40 7 issue a judgment of invalidity of the patent before July 19th
09:05:45 8 of 2010, then the plaintiff cannot get any relief. Their ANDA
09:05:52 9 will not be approved until the pediatric exclusivity that's
09:05:57 10 associated with this patent expires some six months after July
09:06:02 11 2010. And after that the patent is expired and there is no
09:06:05 12 relief to be had.

09:06:07 13 So that's really the source of our suggestion that we
09:06:12 14 stay the case. We're going to give defendants all the
09:06:15 15 discovery we have from that case, all the documents,
09:06:18 16 transcripts, and so on. But then our suggestion is stay the
09:06:22 17 case until we see what happens in Jersey. And then likely,
09:06:29 18 again, there's going to be no time that you can do anything
09:06:34 19 meaningful. If the patent's invalidated, again, in a manner
09:06:39 20 that collaterally estops us, that's the end of this case.

09:06:42 21 If, on the other hand, we get a judgment that the
09:06:45 22 patent's valid, then as a practical matter likely that will
09:06:49 23 decide the fate of all the parties from that point forward.
09:06:53 24 So that's, from our perspective, where we are, your Honor.

09:06:58 25 THE COURT: Okay. Who wants to speak?

09:06:59 1 MR. FELDMAN: I will speak, your Honor.

09:07:00 2 THE COURT: There's questions pending, and he's
09:07:02 3 thrown a few out for you.

09:07:04 4 MR. FELDMAN: Absolutely.

09:07:05 5 Our position is this is an invalid patent. The
09:07:08 6 fellow circuit has already denied them a preliminary
09:07:11 7 injunction in the New Jersey case finding that there's a
09:07:13 8 substantial likelihood that the defendants would, in fact, be
09:07:15 9 able to prove that it was invalid.

09:07:17 10 That case is going to a jury trial, I believe, as he
09:07:20 11 said, anywhere between January and March.

09:07:22 12 Our position is that we would like our day in court.
09:07:27 13 We would like to go to trial prior to the expiration of this
09:07:29 14 patent, so that we will not be restricted by this pediatric
09:07:33 15 exclusivity. What you're talking about is six months of
09:07:36 16 exclusivity. He says it's a \$2 billion a year drug. You can
09:07:39 17 do the math. You're talking about close to a billion dollars'
09:07:42 18 worth of sales for them, if they can block everybody on
09:07:45 19 pediatric exclusivity. The Hatch-Waxman Act was not designed
09:07:50 20 to give them those sorts of boondoggles.

09:07:52 21 It's designed so that the generics can get their
09:07:55 22 products to market as quickly as possible and the public can
09:07:57 23 benefit from that.

09:07:58 24 So our position is, is we will take their discovery
09:08:01 25 from the other case. We'll do whatever cleanup discovery we

09:08:04 1 need to do. We'll do limited expert stuff and basically get
09:08:06 2 our case ready for trial so that we could go to trial at the
09:08:09 3 end of May or beginning of June, if, in fact, that's
09:08:11 4 necessary. If, as he says, it's obviated by the other trial,
09:08:16 5 for example, if the patent's invalid there, then we don't have
09:08:18 6 to go to trial. We won't have to do all this.

09:08:19 7 But, frankly, we're entitled to our day in court.
09:08:22 8 We're not collaterally estopped by that case because we're not
09:08:25 9 part of it and that's what we would like, your Honor.

09:08:26 10 THE COURT: Well, you've seen our new standardized
09:08:28 11 patent rules, right?

09:08:30 12 MR. FELDMAN: Yes, your Honor.

09:08:30 13 THE COURT: Which I worked on with the committee.

09:08:32 14 MR. FELDMAN: Right.

09:08:34 15 THE COURT: And we certainly don't have a trial date
09:08:37 16 within six months of the filing of a suit. So how do you
09:08:40 17 propose that we're going to get through all of the issues plus
09:08:44 18 my ruling on any proposed summary judgment issues before
09:08:51 19 July 15th?

09:08:51 20 MR. FELDMAN: Well, as you know, your Honor, there's
09:08:55 21 an opt-out provision of -- under the local rules for good
09:08:57 22 cause and I think there is good cause here.

09:08:59 23 Again, a lot of the discovery has already been done
09:09:02 24 in the other case. There's not going to be a lot of issues as
09:09:02 25 far as that goes, and we're pretty ready to take on their

09:09:05 1 discovery and look at it and see if there's any cleanup stuff
09:09:07 2 that we need to do.

09:09:08 3 We can propose -- we have, in fact, proposed to them
09:09:10 4 a fairly expedited schedule, which I think is still realistic,
09:09:16 5 you know. The real deciding factor here, though, is you, your
09:09:18 6 Honor, in whether you're willing to give us a trial date in
09:09:22 7 time for you to actually decide the case.

09:09:23 8 THE COURT: Well, and that also includes the fact
09:09:25 9 that I have two monster civil trials scheduled for over a
09:09:30 10 year, one of which begins in March and is an eight-week trial.
09:09:35 11 That's the Paine case, which is a 1983 cause of action,
09:09:40 12 beginning March 13.

09:09:42 13 And it's followed by an Exxon Mobile case, which we
09:09:49 14 anticipate will be another six weeks, which, I believe, is in
09:09:53 15 May.

09:09:54 16 So let me just get those dates. Paine is scheduled
09:09:57 17 to begin -- it's Paine versus City of Chicago, 06-3173, is
09:10:02 18 scheduled to begin March 13th, and go all the way through
09:10:07 19 April 23rd.

09:10:09 20 There is another trial beginning on the 26th of April
09:10:15 21 and another different trial, May 3rd, and then the Exxon
09:10:20 22 Mobile case begins May 10th and is expected to go through to
09:10:25 23 June 4th, and then I'm out June 14 and 21.

09:10:34 24 So I don't know. Let's see. Maybe there's three
09:10:37 25 days -- July 7th, 8th, and 9th -- that are open right now. So

09:10:41 1 we're going to do a three-day trial on your Hatch-Waxman Act
09:10:46 2 case after where are the summary judgments and how are we
09:10:49 3 getting all this done and why did you file so late?

09:10:53 4 MR. FELDMAN: Your Honor, the reason we filed so late
09:10:55 5 is because as the Federal Circuit already found, there's
09:10:59 6 substantial likelihood ...

09:10:59 7 THE COURT: It did what?

09:11:00 8 MR. FELDMAN: The Federal Circuit already found that
09:11:01 9 there's a substantial likelihood that this patent is invalid.
09:11:06 10 We believe it's invalid, having --

09:11:06 11 THE COURT: Did they just do that?

09:11:08 12 MR. FELDMAN: They did it within the last -- we filed
09:11:10 13 shortly after that. That's ...

09:11:14 14 THE COURT: Okay. Any response?

09:11:16 15 MR. O'MALLEY: Yes, your Honor.

09:11:17 16 First of all, the preliminary injunction decision at
09:11:21 17 the District Court level was in July, the summer, I believe,
09:11:26 18 of 2007. So it was prior to them ever filing their ANDA.

09:11:33 19 Now -- and in that District Court opinion, the judge
09:11:36 20 never finds that the patent is likely invalid, nor did the
09:11:40 21 CAFC --

09:11:41 22 THE COURT: The Federal Circuit's decision was in
09:11:43 23 July, did you say?

09:11:44 24 MR. O'MALLEY: The District Court decision.

09:11:46 25 THE COURT: Oh, the District Court.

09:11:47 1 MR. O'MALLEY: It was in summer of 2007. The CAFC
09:11:49 2 decision was -- I don't have that available to me.

09:11:56 3 But in both decisions the Court found only that there
09:12:00 4 was a substantial question as to the delay of the patent. The
09:12:05 5 Federal Circuit just found there was no abuse of discretion
09:12:07 6 and, indeed, found that the District Court had committed error
09:12:10 7 with respect to at least one of its factual findings. So it
09:12:16 8 wasn't that strong.

09:12:16 9 On this point that we're holding up generic
09:12:20 10 competition, that simply isn't true, your Honor. Two generics
09:12:23 11 have launched. The product is already generic. And with
09:12:28 12 respect to those two generics in the District of New Jersey,
09:12:32 13 that's going to be a jury trial, and we have a claim for
09:12:34 14 damages, which will be decided at some point in the future,
09:12:36 15 assuming the patent is upheld, as most active ingredient
09:12:41 16 patents are.

09:12:43 17 MR. FELDMAN: Your Honor, I can give you the cite to
09:12:45 18 the Federal Circuit opinion --

09:12:46 19 THE COURT: Okay.

09:12:46 20 MR. FELDMAN: It is 566 F.3d 999. It's a 2009
09:12:51 21 decision.

09:12:52 22 THE COURT: 566 F.3d what?

09:12:54 23 MR. FELDMAN: 999.

09:12:56 24 THE COURT: 999.

09:12:57 25 MR. O'MALLEY: If I may, one further point on this

09:13:00 1 notion that we have a realistic schedule, we don't see it,
09:13:06 2 your Honor. The day that they have proposed to file
09:13:09 3 dispositive motions is April 26, 2010. And then they proposed
09:13:15 4 the end of May for the trial, which obviously given your own
09:13:19 5 schedule is never going to work. But, I mean, even assuming
09:13:24 6 one could do a three-day trial July 7, 8, 9, then you have a
09:13:29 7 week to issue a bench trial [sic] on a complicated active
09:13:34 8 ingredient patent.

09:13:36 9 In the District of New Jersey there are literally
09:13:40 10 dozens of expert witnesses that potentially are going to
09:13:43 11 appear at trial.

09:13:46 12 THE COURT: Well, I can't give you a ruling on this
09:13:49 13 today, because this is quite a conflict. You're on polar
09:13:55 14 opposites and, you know, certainly if it's a situation that is
09:13:59 15 deserving of being placed on an expedited schedule, which, by
09:14:03 16 the way, there's no motion requesting such a thing.

09:14:07 17 I mean, the case was filed August 19th, and this is
09:14:09 18 the first, you know, common joint status issue that I have
09:14:12 19 read when I got the report. I was surprised there was no
09:14:15 20 expedited motion or any request to move the case along more
09:14:20 21 quickly.

09:14:21 22 So I don't know whether if I do think that it can
09:14:25 23 move along more quickly, based upon the allegations in the
09:14:29 24 complaint, whether I have an obligation to see if there's
09:14:31 25 another Court that can handle it with the trial schedule that

09:14:34 1 is not as booked as mine. I need to look into these issues,
09:14:39 2 and I'll have to do that over the course of the next week.

09:14:43 3 So I will see all of you again -- let's see. This is
09:14:47 4 the holiday week. I'll see you on December 7th at 9:00 a.m.
09:15:00 5 and let you know how we're going to proceed and if we're going
09:15:04 6 to work with any type of schedule that preserves this
09:15:08 7 July 15th end game. And I'll look up the Federal Circuit
09:15:14 8 opinion and see what is there. I thought there were two
09:15:19 9 opinions, someone mentioned to me another opinion.

09:15:22 10 MR. O'MALLEY: Yeah. There was a District Court
09:15:24 11 opinion.

09:15:24 12 THE COURT: Okay.

09:15:25 13 MR. O'MALLEY: I don't know if it was --

09:15:26 14 THE COURT: That's from --

09:15:27 15 MR. FELDMAN: Your Honor, it's actually -- if you'll
09:15:30 16 look at docket 29 that we filed. In the joint status report,
09:15:33 17 all of these are in there.

09:15:34 18 But the cite to the District Court opinion is
09:15:38 19 532 F.Supp.2d 666.

09:15:42 20 THE COURT: How ironic, 666 and 999?

09:15:46 21 Okay. All right, folks. Let me take a look at it
09:15:49 22 and see what I can do. I'm actually sitting on the Seventh
09:15:56 23 Circuit on the -- I mean, the Federal Circuit on the 8th and
09:15:59 24 the 9th. Am I actually in that date or do I fly to D.C.?

09:16:04 25 THE CLERK: 12/7, you're leaving on 12/7.

09:16:08 1 THE COURT: Okay. I think -- but we have a call that
09:16:10 2 morning, right?

09:16:11 3 Okay. So I'll see you before I head to the Federal
09:16:14 4 Circuit. I'll ask them, right? All right. Thank you very
09:16:17 5 much.

6 (Concluded at 9:16 a.m.)

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13 C E R T I F I C A T E

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15 I certify that the foregoing is a correct transcript from
16 the record of proceedings in the above-entitled matter.

17
18 /s/April M. Metzler, RPR, CRR, FCRR November 23, 2009

19 April M. Metzler, RPR, CRR, FCRR Date

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